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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/822,186	03/20/1997	DAVID C RUEGER	CRP-137	6062
7590	02/23/2005		EXAMINER	
JAMES F. HALEY FISH & NEAVE 1251 AVENUE OF THE AMERICAS NEW YORK, NY 100201104			ROMEO, DAVID S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	08/822,186	RUEGER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	David S Romeo	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-6,8,9,11-25,31-33 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) 6,9 and 14 is/are withdrawn from consideration.
- 5) Claim(s) 31 is/are allowed.
- 6) Claim(s) 1,3-5,8,11-13,15,16,20-24,32,33 and 35-38 is/are rejected.
- 7) Claim(s) 17-19,25 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action 5 has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/01/2004 has been entered.

Claims 1, 3-6, 8, 9, 11-25, 31-33, 35-38 are pending. Applicants elected with 10 traverse group III, claims drawn to an osteogenic device comprising an osteogenic protein, cellulose, and a matrix, in Paper No. 45. Applicants elected the species "single osteogenic species OP-1," "single matrix species collagen," and "single cellulose species carboxymethylcellulose" in Paper No. 45. Claims 1, 3-6, 8, 9, 11-16, 20-24, 32, 33, 35, 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), to the extent 15 that they are drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 44. Claims 6, 9, 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

20 Applicants argue that in the Final Office Action of March 4, 2004 or in the Advisory Action of July 14, 2004 the Examiner identify the restriction requirement or the basis for it. Applicant's arguments have been fully considered but they are not persuasive. In the advisory action mailed 07/14/2004 in item 10 the examiner is merely

indicating the status of the claims. The status of the claims and the restriction requirement were also reiterated in the final office action mailed 03/04/2004. Applicants' other arguments have been fully considered. Applicants' amendment has overcome the previous rejections.

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**New Formal Matters, Objections, and/or Rejections:**

***Claim Rejections - 35 USC § 103***

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (CD, cited by Applicants) in view of Sato (U, the paper mailed 08/17/1999) and Ammann (BA, cited by Applicants).

Cook teaches a composite comprising a collagen carrier and rhOP-1 for the healing of segmental defects (Abstract; page 303, left column, full paragraph 1; page 303, right column, full paragraph 1). The composite of carrier and protein was an amorphous material with the consistency of wet sand (paragraph bridging pages 303-304). Cook does not teach a composite comprising CMC.

Sato recognizes that enhancing the plasticity of granular deposits facilitates the filing of bone defects, increases the rate of bone ingrowth, and it's easier to inject into a bone defect, thereby shortening surgery and decreasing bleeding (page 258, right column, full paragraph 1), makes the composite easier to handle (Abstract), a viscous carrier may lessen the difficulty of filing bone defects homogeneously with granular deposits (page 259, right column, full paragraph 1).

Ammann recognizes the desirability of providing a formulation with the proper consistency suitable for molding to fill in bone gaps where needed (page 8, last full

paragraph) and providing a formulation with enhanced consistency for improved application to the desired bone defect site (page 9, full paragraph 3). Ammann exemplifies this teaching with TGF- $\beta$  and TCP granules (page 9, full paragraph 5). The "polymer for enhancing consistency of the formulation" may be any polysaccharide or

5 insoluble protein material useful for binding the TGF- $\beta$  to the TCP to form a smooth, moldable putty or paste. Especially preferred are carbohydrates such as cellulose and cellulose derivatives such as carboxymethyl cellulose.

Sato and Ammann do not teach a device comprising rhOP-1, collagen and CMC.

However, it would have been obvious to one of ordinary skill in the art at the time of

- 10 Applicants' invention to make an amorphous composite with the consistency of wet sand comprising collagen and rhOP-1, as taught by Cook, and to modify that teaching by adding CMC, as taught by Ammann, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification one of ordinary skill in the art would have a reasonable expectation that enhancing the consistency of a
- 15 composite by making a smooth, moldable putty or paste would fill in bone gaps where needed, improve application to the desired bone defect site, make the composite easier to handle, and lessen the difficulty of filling bone defects homogeneously with granular deposits. The invention is *prima facie* obvious over the prior art.

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***Claim Rejections - 35 USC § 112***

Claims 1, 3, 5, 8, 11-13, 15, 16, 20-24, 32, 33, 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they recite the term “non-polymeric, non-synthetic matrix.” Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of “non-polymeric, non-synthetic matrix” an artisan cannot determine what additional or material

5 limitations are placed upon a claim by the presence of this element. The specification provides no guidance that would allow those skilled in the art to determine, with a reasonable degree of confidence, whether any given matrix was “non-polymeric, non-synthetic.” Furthermore, the art recognizes that collagen and tricalcium phosphate are polymers or polymeric. See Kuberampath (U. S. Patent No. 5,674,844; column 21, lines 39-41). It is unclear when a material is to be considered polymeric and when it is to be considered non-polymeric. The metes and bounds are not clearly set forth.

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Claims 32, 33, 35, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

15 which applicant regards as the invention.

According to the present specification, the terms “bone morphogenic protein” and “BMP” embrace the class of proteins typified by human osteogenic protein 1 (hOP-1) (page 5, lines 11-14). In other words, the terms “bone morphogenic protein” and “BMP” include but are not limited to the class of proteins typified by human osteogenic protein 1 (hOP-1). Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of “bone morphogenic protein” an artisan cannot determine what additional or material limitations

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are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

### *Claim Objections*

5       Claims 17-19, 25 are objected to because of the following informalities: there is a missing parentheses and/or a misplaced period after "(w/v" (claim 17, line 6). Appropriate correction is required.

### *Conclusion*

10      Claim 31 is allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

15      IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

20      FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

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DSR  
FEBRUARY 15, 2005